

107



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,326	10/15/2001	Piero Del Soldato	108907-00020	5184

4372 7590 05/05/2004

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EXAMINER

RAYMOND, RICHARD L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,326	DEL SOLDATO, PIERO	
	Examiner	Art Unit	
	Richard L. Raymond	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment of February 5, 2004 canceled claims 1-10 and added new claims 11-16. Accordingly, the claims now under consideration are claims 11-16.
2. The Section 112, second paragraph, rejection of record has been overcome by applicants' response.
3. While lack of unity was not indicated in applicants' corresponding PCT application, it is noted that the International Preliminary Examination Report therein states that a meaningful search of the whole scope claimed was not possible and was not done due to the large number of compounds encompassed. The present requirement for election of species is maintained as is the improper Markush rejection below.

Improper Markush Rejection

4. Claims 11-16 are rejected as being improper Markush claims in the definition of the B-C linker for the reasons of record and herein expanded to include the A group. So substituted, the resulting total compounds (A-B-C-NO₂) lack a common core and are structurally diverse and patentable distinct one from the others. Note the myriad possibilities for the T₁, T_b T_{b1}, T_c and Y linking groups and the vast number of drugs encompassed by the R and X₂ variables. A reference anticipating one under 35 USC 102 would not be a reference against the others under 35 USC 103. Additionally, an undue search burden exists because of this structural diversity. A large number of

classes and subclasses are involved in the U.S. classification system (classes 540, 544, 546, 548, 549, 558, 560, 562, 564 and 568 and corresponding subclasses in use class 514) in addition to the diverse structure searches in STN/CAS.

Claim Rejections - 35 USC § 112

5. Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain drugs linked by certain linking groups, does not reasonably provide enablement for all drugs and enumerable combinations of linking groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. See the discussion in the improper Markush rejection above.

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The definition of the claimed compounds by way of the desired properties shown by various tests render the claims indefinite. Compounds must be fully defined by nomenclature or structural formula. Reference to methods and properties obtained is not sufficient.

Conclusion

7. Applicants' related U.S. Patent No. 5,861,426 is made of record.


8. This action is not made final.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard L. Raymond whose telephone number is (571) 272-0673. The examiner can normally be reached on Monday-Thursday (9:30AM-8:00PM)).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard L. Raymond
Primary Examiner
Art Unit 1624

rr
May 3, 2004